II. REMARKS

Formal Matters

Claims 30-36, 38-43, 45, 57-61, 63, 65-75, and 77-96 are pending after entry of the amendments set forth herein.

Claims 30-87 were examined and were rejected.

Claims 30, 31, 33, 36, 38-40, 43, 45, 55, 57, 60, 63, 69, 73, 74, and 77-79 are amended. The amendments to the claims were made solely in the interest of expediting prosecution, and are not to be construed as an acquiescence to any objection or rejection of any claim. Support for the amendments to claims 30, 31, 33, 36, 38-40, 43, 45, 55, 57, 60, 63, 69, 73, 74, and 77-79 is found in the claims as originally filed, and throughout the specification, in particular at the following exemplary locations: page 6, lines 23-26. Accordingly, no new matter is added by these amendments.

Claims 37, 44, 46-54, 56, 62, 64, and 76 are canceled without prejudice to renewal, without intent to acquiesce to any rejection, and without intent to surrender any subject matter encompassed by the canceled claims. Applicants expressly reserve the right to pursue any canceled subject matter in one or more continuation and/or divisional applications.

Claims 88-96 are added. Support for new claims 88-96 is found in the claims as originally filed, and throughout the specification, including the following exemplary locations: page 6, lines 8-11; page 6, lines 17-18; page 6, lines 23-26; page 8, lines 9-16; page 9, lines 4-5; and page 9, lines 14-16. Accordingly, no new matter is added by these new claims.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

PTO SB-08A form

Applicants respectfully request that the Examiner initial and return the PTO SB-08A forms submitted with the Information Disclosure Statements filed on April 14, 2004 in this application, thereby indicating that the references cited therein have been reviewed and made of record.

Withdrawn rejections

Applicants note with gratitude that the following rejections, raised in the Office Action dated May 5, 2003, were not reiterated in the final Office Action, and have been withdrawn: 1) the rejection of

claims 31-36, 50, and 54 under 35 U.S.C.§112, second paragraph; the rejection of claims 30, 37-53, 55, and 56 under 35 U.S.C.§101; and the rejection of claims 45-50 under 35 U.S.C.§103.

Rejection under 35 U.S.C.§112, second paragraph

Claims 31-36 and 69-72 were rejected under 35 U.S.C.§112, second paragraph, as allegedly indefinite. Claims 60, 61, 63, and 65-68 were rejected under 35 U.S.C.§112, second paragraph, as allegedly indefinite.

The final Office Action stated that claim 31 recites "encodes a functional domain of glycosyl sulfotransferase-3"; and claim 60 recites "comprises a functional domain of glycosyl sulfotransferase-3." The final Office Action stated that the metes and bounds of the recited phrases are not clear.

Functional domains of glycosyl sulfotransferase-3 (GST-3) polypeptides are amply described in the specification. Specification, page 8, lines 9-16 and page 38, lines 12-26. For example, the specification discusses a sulfate acceptor binding site, and a sulfate donor binding site. Specification, page 8, lines 9-16 and page 38, lines 12-26. Accordingly, the claims are clear and need not be amended.

Nevertheless, without conceding as to the correctness of this rejection, and solely in the interest of expediting prosecution, the phrase "encodes a functional domain of glycosyl sulfotransferase-3" in claim 31, and the phrase "comprises a functional domain of glycosyl sulfotransferase-3" in claim 60 are deleted.

Applicants submit that the rejection of claims 31-36 and 69-72, and claims 60, 61, 63, and 65-68, under 35 U.S.C. §112, second paragraph, has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

Rejections under 35 U.S.C.§112, first paragraph

Claims 60, 61, 63, 65, 69, 71, 72, 30-37, 39-56, and 73-75 were rejected under 35 U.S.C.§112, first paragraph, as allegedly lacking enablement. Claims 31-36, 51-54, 60, 61, 63, 69, 73, and 74 were rejected under 35 U.S.C.§112, first paragraph, as allegedly lacking written description.

Enablement

The Office Action stated that the specification does not reasonably provide enablement for a DNA that hybridizes to SEQ ID NO:1 under stringent conditions, wherein said polynucleotide encodes a functional domain of GST-3, or any polynucleotide comprising a fragment of at least 25 nucleotides of a nucleotide sequence having at least 90% nucleotide sequence identity to SEQ ID NO:1. Applicants respectfully traverse the rejection.

The instant specification teaches how to make the claimed nucleic acids, and how to use the claimed nucleic acids. Those skilled in the art, given the guidance provided in the specification, coupled with the extensive knowledge and skill level of those in the art, could readily make and use the nucleic acids as claimed.

For example, as noted above, the specification discusses various functional domains of GST-3 polypeptides, including, e.g., a sulfate acceptor binding site, and a sulfate donor binding site. Specification, page 8, lines 9-16 and page 38, lines 12-26. Amino acid sequences of various functional domains are provided. Specification, page 38, lines 12-26. Those skilled in the art, given such guidance and given the knowledge and skill level of those skilled in the art, could readily make and use nucleic acids comprising nucleotide sequences encoding such functional domains.

Those skilled in the art could readily make nucleic acid fragments and nucleic acid variants that encode GST-3 functional domains. Those skilled in the art were well aware, as of the priority date of the instant application, of a variety of techniques for manipulating nucleic acids (e.g., making nucleic acid variants, and making nucleic acid fragments). Such manipulations were routine in the art. Those skilled in the art were well aware, as of the priority date of the instant application, of methods for producing, in a host cell, a polypeptide encoded by a nucleic acid. Such methods for production of polypeptides were routine. The instant specification teaches how to identify GST-3 functional domains. Thus, making and preparing nucleic acids and nucleic acid variants was routine; producing a polypeptide encoded by a nucleic acid was routine; and testing of the encoded polypeptides would have involved nothing more than following the guidance provided in the specification. Accordingly, the specification is enabling for the full scope of the instant claims.

The sequences of nucleic acids encoding GST-3 functional domains are determined through

routine experimentation, typically employing nothing more than functional assays (e.g., sulfate acceptor binding; sulfate donor binding) on a variety of sequence variants of the polypeptide made by routine recombinant DNA techniques. Binding assays were well known to those skilled in the art as of the priority date of the instant application. Since these experiments are routine in nature, no undue experimentation is required. In other words, the only experimentation that may be required to enable the claimed invention are those experiments to determine the presence of a certain activity (e.g., sulfate acceptor binding; sulfate donor binding), and since this only requires a routine assay on polypeptide variants to determine the functional fragments and/or functional variants, no undue experimentation is necessary.

Applicants note that the claims are amended to recite nucleic acids comprising nucleotide sequences that encode a polypeptide that catalyzes the transfer of a sulfate group from a sulfate donor to a sulfate acceptor.

Those skilled in the art could readily make nucleic acid fragments and nucleic acid variants that encode a GST-3 polypeptide (including GST-3 polypeptide fragments) that catalyze the transfer of a sulfate group from a sulfate donor to a sulfate acceptor. Those skilled in the art were well aware, as of the priority date of the instant application, of a variety of techniques for manipulating nucleic acids (e.g., making nucleic acid variants). Such manipulations were routine in the art. Those skilled in the art were well aware, as of the priority date of the instant application, of methods for producing, in a host cell, a polypeptide encoded by a nucleic acid. Such methods for production of polypeptides were routine. The instant specification teaches how to determine whether a given polypeptide catalyzes the transfer of a sulfate group from a sulfate donor to a sulfate acceptor. Thus, making and preparing nucleic acids and nucleic acid variants was routine; producing a polypeptide encoded by a nucleic acid was routine; and testing of the encoded polypeptides would have involved nothing more than following the guidance provided in the specification. Accordingly, the specification is enabling for the full scope of the instant claims.

The only experiments, if any, that need be performed to enable the entire scope of the claim are those designed to determine whether a given polypeptide fragment (e.g., encoded by a claimed nucleic acid) catalyzes transfer of a sulfate group from a sulfate donor to a sulfate acceptor. Adequate guidance is provided in the specification, and relevant information was known to those skilled in the art. For

example, the specification provides a description of an assay for determining whether a polypeptide catalyzes transfer of a sulfate group from a sulfate donor to a sulfate acceptor. See, e.g., specification, page 39, under the heading "VII. GST-3 sulfates Glycam-1." Any experimentation, if necessary, would involve routine techniques well known to those skilled in the art.

The sequences of nucleic acids encoding polypeptides that catalyze the transfer of a sulfate group from a sulfate donor to a sulfate acceptor are determined through routine experimentation, typically employing nothing more than performing the same assay disclosed in the specification on a variety of sequence variants of the polypeptide made by routine recombinant DNA techniques. Since these experiments are routine in nature, no undue experimentation is required. In other words, the only experimentation that may be required to enable the claimed invention are those experiments to determine the presence of a certain activity (catalyzing the transfer of a sulfate group from a sulfate donor to a sulfate acceptor), and since this only requires a routine assay on polypeptide variants to determine the active fragments and/or active variants, no undue experimentation is necessary.

Written description

The Office Action stated that the specification does not contain any disclosure of the function of all DNA sequences encompassed by the claims or the amino acid sequences encoded by said DNA sequences. Applicants respectfully traverse the rejection.

Consideration of the standards for written description

The Revised Interim Guidelines for Examination of Patent Applications Under 35 U.S.C. §112, paragraph 1 "Written Description" Requirement, (*Federal Register* (Dec. 21, 1999) Vol. 64 (No. 244):71427-71440) ("Revised Guidelines"), state:

(1) There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed;

(2) the Office has the initial burden of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims;

(3) Consequently, rejection of an original claim for lack of written description should be rare;

(4) an Examiner should review the entire application to understand what the applicant has described as the essential features of the invention; and

(5) the Examiner's review of the application is to be conducted *from a standpoint of one of skill*

in the art at the time the application was filed and should include a determination of the field of the invention and the level of skill and knowledge in the art (emphasis added). Revised Guidelines, at page 71435.

The Office Action has not presented sufficient evidence or reasons why a person skilled in the art would not recognize that the written description of the claimed invention provides support for the claims.

As stated in the Revised Guidelines, "In most technologies which are mature, and *wherein the knowledge and level of skill in the art is high*, a written description question should not be raised for original claims even if the specification discloses only a method of making the invention and the function of the invention." Revised Guidelines, page 71436. The written description guidelines are based in part on *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir.1997). It should be remembered that *University of California v. Eli Lilly and Co.*, (Fed. Cir.1997) was based on a patent that was filed in 1977, i.e., over 20 years ago, when the level of skill in the art was not at the level that it was as of the filing date of the instant application.

The purpose of the written description requirement is to ensure that the specification conveys to those skilled in the art that the applicants possessed the claimed subject matter as of the filing date sought. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d (BNA) 1111, 1117 (Fed. Cir. 1991). *See also All Dental Prodx, LLC v. Advantage Dental Products, Inc.*, 2002 U.S. App. LEXIS 22372, *10-11 (Fed. Cir. October 25, 2002) (the specification must simply indicate to persons skilled in the art that as of the [filing] date the applicant had invented what is now claimed."). Thus, the test for whether a claimed invention is adequately described has often been stated as whether or not one of skill in the art would have understood from the specification that an applicant possessed the claimed subject matter when the specification was filed. *See, e.g., Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575, 227 U.S.P.Q. (BNA) 177, 179 (Fed. Cir. 1985). Whether the specification meets the written description requirement for the claimed invention is a question of fact. *Vas-Cath,* 935 F.2d at 1563, 19 U.S.P.Q.2d (BNA) at 1116.

The written description requirement of 35 U.S.C.§112, first paragraph, does not require that Applicants disclose the function of all DNA sequences encompassed by the claims or the amino acid sequences encoded by the DNA sequences.

The specification provides the sequence of SEQ ID NO:01. Thus, the specification provides adequate written description of functional domains of GST-3. As noted above, the specification amply describes functional domains of GST-3, including, e.g., a sulfate acceptor binding site, and a sulfate donor binding site. Specification, page 8, lines 9-16 and page 38, lines 12-26. Those skilled in the art, given the description in the specification, would reasonably conclude that Applicants had, as of the priority date of the instant application, possession of the claimed invention. Furthermore, Applicants note that the claims recite both functional and a structural components, and that such functional and structural components are described in the specification. Accordingly, the instant specification provides adequate written description for the claimed invention.

Applicants note that the claims are amended to recite nucleic acids comprising nucleotide sequences that encode a polypeptide that catalyzes the transfer of a sulfate group from a sulfate donor to a sulfate acceptor. *The instant claims recite both structural and functional components, and such structural and functional components are described in the specification.*

The specification provides the sequence of SEQ ID NO:01. Thus, the specification provides adequate written description of nucleic acids comprising a fragment of at least about 25 contiguous nucleotides of a nucleotide sequence having at least about 90% nucleic acid sequence identity to SEQ ID NO:01, wherein the fragment encodes a polypeptide that catalyzes the transfer of a sulfate group from a sulfate donor to a sulfate acceptor. Those skilled in the art, given the description in the specification, would reasonably conclude that Applicants had, as of the priority date of the instant application, possession of the claimed invention. Accordingly, the instant specification provides adequate written description for the claimed invention.

Conclusion as to the rejections under 35 U.S.C.§112, first paragraph

Applicants submit that the rejection of the claims discussed above under 35 U.S.C. §112, first paragraph, has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

Obviousness-type double patenting

Claims 30-87 were rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over claims 1-6 of U.S. Patent No. 6,265,192. Applicants enclose herewith a

terminal disclaimer, disclaiming patent term beyond the expiration date of U.S. Patent No. 6,265,192. Thus, this rejection of claims 30-87may be withdrawn.

Claims 30-87 were rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over claims 5-10 and 12 of U.S. Patent Application No. 10/007,262, published as U.S. 2002/0164748.

Applicants note that claims 5-10 and 12 were canceled without prejudice to renewal in a Preliminary Amendment filed on November 8, 2001 in the 10/007,262 case. Accordingly, there is no need to file a Terminal Disclaimer over claims 5-10 and 12 of the 10/007,262 case, and this rejection may be withdrawn.

III. CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number UCAL107CON.

Respectfully submitted,
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Date: April 15, 2004

By: _____
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